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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,305	09/28/2001	Jennifer Richardson	07334-312001 / MPI2000-31	5199
26161	7590	02/23/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 02/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/967,305

Applicant(s)

RICHARDSON ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34 and 59-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34 and 59-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>02/17/06</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 33-34, 59-79 are being examined.

The following are the remaining rejections.

OBJECTION

Claims 33-34, 59-79 are objected to, because the meaning of the language "prostate tumor cells encoding" a protein having the amino acid sequence of SEQ ID NO:2" in claim 33 is not clear. The language "encoding a protein" is conventionally used in the art, when referring to "a polynucleotide" encoding a polypeptide, in view that a specific DNA molecule carries the genetic information, whereby particular combinations of three adjacent nucleotides in a DNA control the insertion of a particular amino acid in equivalent places in a protein molecule (Stedman's medical dictionary, 25th ed, 1990, p.323).

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term, In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

For the purpose of compact prosecution, it is assumed that claim 33 refers to prostate tumor cells overexpressing the nucleotide sequence, SEQ ID NO:3, encoding the protein having the amino acid sequence of SEQ ID NO:2.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAHP, NEW MATTER, NEW
REJECTION**

Claims 33-34, 59-79 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of "prostate tumor cells encoding" a protein having the amino acid sequence of SEQ ID NO:2" claimed in Claims 33-34, 59-79 has no clear support in the specification and the claims as originally filed.

A review of the specification discloses support for "the nucleotide sequence of cDNAs encoding human alpha-methylacyl-CoA racemases are shown in SEQ ID NO:1, 3 and 4" (p.2, lines 1-3).

There is nothing in the specification to suggest or to mention obtaining a test sample comprising "prostate tumor cells encoding" a protein having the amino acid sequence of SEQ ID NO:2".

The subject matter claimed in claims 33-34, 59-79 broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 103

Claims 33-34, 59-79 remain rejected under 35 uSC 103, as being obvious of US 6,395,278 B1 in view of US 5,968,737, Sambrook et al, and Ramsay et al, for reasons already of record in paper of 08/25/05.

Applicant argues that nothing in the cited references suggest the use of such prostate cells, which encode a protein having the amino acid sequence of SEQ ID

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NO:2. Applicant argues that at most US 5,968,737 suggests the use of cells encoding a different protein, in view that the sequence cited in US 5,968,737 encodes a different protein than SEQ ID NO:2.

Applicant arguments in paper of 11/16/05 have been considered but are not found to be persuasive for the following reasons:

For the purpose of compact prosecution, it is assumed that claim 33 refers to prostate tumor cells overexpressing the nucleotide sequence, SEQ ID NO:3, encoding the protein having the amino acid sequence of SEQ ID NO:2.

The specification discloses overexpression of SEQ ID NO:3 encoding SEQ ID NO:2 in prostate tumor tissue (Example 1, on p.12-14, and Tables 1-4).

There is nothing in the specification that teaches that there exists a specific population of prostate tumor tissues that do not overexpress SEQ ID NO:3 encoding SEQ ID NO:2, and which are not used in the assay for identifying candidate therapeutic agents.

The prostate tumor cells for use in the claimed method seem to be the same the prostate tumor cells used by US 6,395,278 B1.

Although the reference does not specifically teach that the prostate tumor cells encode a protein having the amino acid sequence of SEQ ID NO:2, however, the prostate tumor cells for use in the claimed method appear to be the same as the prior art prostate cancer cells, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural

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and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

February 17, 2006

Lusan Unger
Susan Unger
Primary Patent Examiner